IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF IOWA
CEDAR RAPIDS DIVISION

STATE OF KANSAS, STATE OF SOUTH CAROLINA, STATE OF IOWA, STATE OF ALABAMA, STATE OF ALASKA, STATE OF ARKANSAS, STATE OF FLORIDA, STATE OF GEORGIA, STATE OF IDAHO, STATE OF INDIANA, COMMONWEALTH OF KENTUCKY, STATE OF MISSOURI, STATE OF MONTANA, STATE OF NEBRASKA, STATE OF OKLAHOMA, STATE OF NORTH DAKOTA, STATE OF SOUTH DAKOTA, STATE OF UTAH, COMMONWEALTH OF VIRGINIA, STATE OF WEST VIRGINIA, LEADINGAGE KANSAS, LEADINGAGE SOUTH CAROLINA, LEADINGAGE IOWA, LEADINGAGE COLORADO, LEADINGAGE MARYLAND, LEADINGAGE MICHIGAN, LEADINGAGE MINNESOTA, LEADINGAGE MISSOURI, LEADINGAGE NEBRASKA, LEADINGAGE NEW JERSEY/DELAWARE, LEADINGAGE OHIO, LEADINGAGE OKLAHOMA, LEADINGAGE PA, SOUTH DAKOTA ASSOCIATION OF HEALTHCARE ORGANIZATIONS, LEADINGAGE SOUTHEAST, LEADINGAGE TENNESSEE, LEADINGAGE VIRGINIA, DOOLEY CENTER, WESLEY TOWERS, *Plaintiffs*, v. XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; CENTERS FOR MEDICARE & MEDICAID SERVICES; and CHIQUITA BROOKS-LASURE, in her official capacity of Administrator of the Centers for Medicare and Medicaid Services, *Defendants*.	Civil Action No. 1:24-cv-00110 **MEMORANDUM IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION**

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INTRODUCTION

The Biden-Harris administration forced upon the nursing home industry a new Rule entitled "Medicare and Medicaid Programs; Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting" ("the Final Rule"). *See* 89 Fed. Reg. 40876 (May 10, 2024). This Final Rule will result in many nursing homes shutting down and leaving their patients with nowhere to go. It will also cost *at least* $43 billion in compliance.

No one is against the best possible care for seniors and residents of long-term care facilities. And nursing homes provide a valuable service to senior citizens when their families are unable to bear the burden of taking care of them. But no one benefits when nice-sounding requirements that could aid seniors are imposed but unachievable, rendering many such facilities out-of-compliance. Then, the likely result is that many facilities that are doing their best to ensure safe and competent care for those who need it may be unable to do so at all—and thus shut down. That is why Congress is tasked with setting the ground rules for such care—and why it is so important that rules be rational and achievable, to avoid denying necessary care to seniors.

This Final Rule is the opposite of rational and achievable and inflicts harm to everyone required to abide by it. Plaintiffs represent a diverse group of States and organizations with nursing homes as members that are already harmed by the Final Rule as it represents an existential threat to nursing homes around the country. Without an injunction, the Final Rule will impose irreparable harm on Plaintiffs now and in the future.

Over fifty years ago, Congress established two staffing requirements for nursing homes participating in both Medicare and Medicaid. *First*, these nursing homes "must use the services of a registered professional nurse [("RN")] for at least 8 consecutive hours a day, 7 days a week." 42 U.S.C. § 1396r(b)(4)(C)(i); *id.* § 1395i-3(b)(4)(C)(i). *Second*, Congress established a flexible staffing standard that requires a nursing home "[to] provide 24-hour licensed nursing services which are sufficient to meet the nursing needs of its residents." *Id.* § 1396r(b)(4)(C)(i); *id.* § 1395i-3(b)(4)(C)(i). For decades, Congress, the Centers for Medicare & Medicare Services ("CMS"), and its predecessors have considered—and rejected—proposals to replace the flexible

staffing standards with a one-size-fits-all staffing requirement. This was for good reason as CMS was never statutorily authorized to do so and any serious examination of such requirements demonstrates their pitfalls.

Earlier this year, Defendants decided to abruptly change course and unilaterally override those laws. They imposed a staffing mandate that tripled Congress's standard for RN care, imposed an inflexible staffing mandate without consideration of the particular community, and required a new, vague "enhanced facility assessment" ("EFA") through the Final Rule. *See* 89 Fed. Reg. 40876.

Because the Final Rule is likely to be held unlawful on a host of grounds, and it causes irreparable harm to both organizational and State plaintiffs here, Plaintiffs need injunctive relief. Preliminary injunctive relief is available where plaintiffs demonstrate (1) a probability or likelihood of success on the merits, (2) real threat of irreparable harm or injury absent immediate relief, (3) that the balance of equities resulting from the issuance of the injunction against the order's effect on the defendant and third parties weighs in favor of plaintiffs, and (4) that the public interest favors immediate injunctive relief. *See Dataphase Sys., Inc. v. C L Sys., Inc.*, 640 F.2d 109, 113 (8th Cir. 1981) (en banc). Plaintiffs meet each of these factors.

Plaintiffs are likely to succeed on the merits because the Final Rule exceeds Defendants' statutory authority. The Final Rule invokes the major questions doctrine because the $43 billion cost and the breadth of authority exerted make it an issue of vast economic and political significance without Congress "speak[ing] clearly" to the issue, which is violates that doctrine. *See Nat'l Fed'n of Indep. Bus. v. Dep't of Lab., Occupational Safety & Health Admin.*, 595 U.S. 109, 117 (2022).

Indeed, the Final Rule lacks plausible, much less clear, authorization. *First*, the Final Rule replaces Congress's directive for an RN to be present for 8 hours per day, 7 days a week ("8/7 requirement"), with a new mandate to have an RN "onsite [for] 24 hours per day, for 7 days a week" ("24/7 requirement"). 89 Fed. Reg. 40876, 40898. *Second*, the Final Rule abandons the flexible statutory staffing standard that is "Sufficient to meet the nursing needs" of each facility's residents, 42 U.S.C. 1396r(b)(4)(C)(i); *accord id.* § 1395i-3(b)(4)(C)(i), to a three-part national

requirement—irrespective of facility needs, current staffing capacity, or state law minimum staffing standards. The Final Rule requires (1) total nurse staffing of at least 3.48 hours per resident day ("HPRD"); (2) a mandate for RN staffing of at least 0.55 HPRD; and (3) nurse aid ("NA") staffing of at least 2.45 HPRD.[1] 89 Fed. Reg. at 40877. Essentially, the Final Rule abandons Congress's *qualitative* and flexible staffing standard for CMS's *quantitative r*equirement that does not account for resident acuity or individual nursing home staff capacity.

CMS identifies no applicable statutory authority to promulgate the Final Rule, instead attempting to justify its actions based on broadly worded provisions and a "miscellaneous" provision that allows the Secretary of the U.S. Department of Health and Human Services (the "Secretary") to impose "such other requirements relating to the health and safety of residents or relating to the physical facilities thereof as the Secretary may find necessary." 42 U.S.C. § 1395i-3(d)(4)(B); *accord id.* § 1396r(d)(4)(B). This vague statutory provision does not allow CMS to promulgate a Final Rule that clashes with a separate direct congressional mandate.

Even if Defendants had the authority to issue such a far-reaching Final Rule, a rule cannot contradict the very statute it claims to interpret. Yet that is exactly what they did here by violating Congress' clear command to have *some* nursing homes not be subject to a 24-hour staffing requirement without a waiver. It also limits waivers to only an 8-hour reprieve from the 24-hour requirement when Congress by statute intended for waivers to go below that.

Beyond the statutory problems with the Final Rule, it is also arbitrary and capricious rulemaking because (1) it represents a sharp departure from past CMS policy without reasoned explanation, (2) CMS did not consider reliance interests when promulgating the Final Rule, and (3) CMS did not consider important aspects of the problem such as the cost and virtual impossibility of complying with the Final Rule. In short, there is no universe in which this Final Rule is lawful.

[1] HPRD is defined as the "total number of hours worked by each type of staff divided by the total number of residents as calculated by CMS." *Id.*

The Final Rule causes severe and irreparable harm to both organizational and State Plaintiffs here. The staffing mandates are impossible for many nursing homes to comply with due to the widespread staffing shortages and massive expenses, which will result in nursing homes reducing capacity and even closing. Although the Final Rule claims to have an extended implementation period, many nursing homes bear those costs *now*.

That is because the Final Rule already requires nursing homes to conduct unreasonable enhanced facility assessments ("EFAs"). Those assessments are costing each nursing significant resources and labor to comply. And although the staffing requirements have a 2-3-year implementation period depending on the region, the reality of a tight labor market requires nursing homes to hire *immediately* because the available supply of nurses will dwindle as the implementation date approaches. Some nursing homes have had to immediately increase their staffing and incurred significant costs to do so. Similarly, states have their own enhanced reporting requirements for their Medicaid programs. Although CMS claims to have a delayed implementation period for this portion of the Final Rule, states have also had to start immediately implementing these requirements. The Final Rule acknowledges this fact by pointing to costs states will incur at year one. In addition, Plaintiff States face immediate and irreparable compliance costs because some of them also have state run LTC facilities that must comply with the Final Rule and all have to comply with enhanced reporting requirements.

Finally, the balance of equities and the public interest weigh in favor of immediate relief. Neither Defendants nor the public will suffer harm from preliminarily enjoining standards where the implementation has not yet occurred, while Plaintiffs are having to undertake significant expenses to conduct EFAs now and in preparation for staffing mandates that will be extraordinarily onerous for many nursing homes to implement. Accordingly, Plaintiffs ask this Court to preliminary enjoin the Final Rule to spare them the irreparable harm they are already facing and will continue to face again.

BACKGROUND

A. Congress enacts statutes that specify staffing requirements for LTC facilities

In 1965, Congress established the Medicare and Medicaid programs by amending the Social Security Act. See Pub. L. No. 89-97, 79 Stat. 286 (July 30, 1965). Nursing homes that participate in Medicare must comply with the statutory requirements for "skilled nursing facilities" ("SNFs"), 42 U.S.C. § 1395i-3, while those participating in Medicaid must meet similar requirements for "nursing facilities" ("NFs"), 42 U.S.C. § 1396r. Because the statutory requirements for both SNFs and NFs are largely parallel, these facilities are often collectively referred to as "long-term care" ("LTC") facilities. CMS has issued consolidated regulations applicable to all LTC facilities participating in Medicare and/or Medicaid. *E.g.*, 42 C.F.R. § 483.1. Both statutes require LTC facilities to use the services of a registered professional nurse for "at least 8 consecutive hours a day, 7 days a week," and to provide 24-hour licensed nursing services that are "sufficient to meet the nursing needs of their residents." 42 U.S.C. § 1395i-3(b)(4)(C)(i) (Medicaid); 42 U.S.C. § 1396r(b)(4)(C)(i)(I)-(II) (Medicaid). There are no staffing quotas within the statutes.

Both statutes authorize waivers of these requirements. Under the Medicare statute, the Secretary may waive the requirement for LTC facilities to employ an RN for more than 40 hours per week if: (1) the facility is "located in a rural area and the supply of skilled nursing services is not sufficient to meet the needs" of local residents; (2) "the facility has one full-time [RN] who is regularly on duty at [the LTC] for 40 hours [per] week"; (3) the LTC facility has patients whose physicians have shown that they do not require an RN or physician for 48 hours, or it has arranged for an RN or physician to provide necessary services when the full-time RN is not on duty; (4) "the Secretary provides notice of the waiver to the State long-term care ombudsman …"; and (5) the facility that is granted the waiver notifies residents and their families of the waiver. *See generally* 42 U.S.C. § 1395i-3(b)(4)(C)(ii)(I)-(V).

Under the Medicaid statute, a state may waive the staffing requirements for an LTC facility if: (1) the LTC facility demonstrates that, despite diligent efforts, it was unable to recruit

appropriate personnel; (2) granting a waiver will not endanger the health or safety of the LTC facility's residents; (3) during times when an RN is unavailable, an RN or physician must be able to respond to calls from the LTC facility; (4) the state agency notifies the state long term care ombudsman of the waiver; and (5) the LTC facility informs its residents and family of the waiver. *See* 42 U.S.C. § 1396r(b)(4)(C)(ii)(I)-(V).

B. Congress did not to impose inflexible staffing mandates

After Congress amended the Social Security Act to declare that all LTC facilities participating in Medicare or Medicaid provide "24-hour nurse service[s] which is sufficient" to meet patient needs, including employing at least one registered professional nurse full-time. Pub. L. No. 92-603, § 278, 86 Stat. 1329, 1424-27 (1972) it also introduced nurse-staffing waiver provisions for rural facilities under specific conditions. *See id.* § 267, 86 Stat. at 1450. The Department of Health, Education and Welfare (predecessor of HHS), through its Social Security Administration ("SSA") proposed regulations in 1973 that aligned with these statutory requirements. *See* 38 Fed. Reg. 18,620 (July 12, 1973). For decades, Congress and federal agencies have repeatedly rejected attempts to impose any inflexible staffing mandate that would override these provisions. During the notice-and-comment period for the 1973 regulations, the SSA received comments urging it to deviate from Congress's flexible (qualitative) approach for a staffing requirement that all nursing homes implement a rigid (quantitative) nurse-to-patient ratio. *See* 39 Fed. Reg. 2,238, 2,239 (Jan. 17, 1974). The SSA rejected such an approach, citing the variability in facility needs and the potential negative impacts of arbitrary staffing quotas. *Id.* SSA reasoned that "the variation from facility to facility in the composition of its nursing staff, physical layout, patient needs and the services necessary to meet those needs precludes setting [a specific ratio]." *Id.*

In 1980, HHS took over the administration of Medicare and Medicaid services but the standard on staffing remained the same. It proposed a "general revision" of the regulation governing the participation of LTC facilities in Medicare and Medicaid. *See* 45 Fed. Reg. 47,368 (July 14, 1980). HHS declined to implement any specific staffing ratios. *Id.* at 47371; *see also id.* at

47387. In 1987, Congress—and not HHS—redefined nursing home categories and imposed uniform staffing requirements on LTC facilities under Medicare and Medicaid by requiring a registered nurse on duty for at least eight hours per day, seven days a week. *See* Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, § 4201(a), 101 Stat. 1330-161; *accord id.* § 4211(a), 101 Stat. 1330-186 (Dec. 22, 1987). Congress included waiver provisions and commissioned studies to analyze staffing requirements—in particular "the appropriateness of establishing minimum caregiver to resident ratios." *See* Pub. L. No. 101-508, §§ 4008(h), 4801(a), 104 Stat. 1338 (1990)). Congress implemented no mandatory ratios or staffing requirements, and CMS continuously administered the staffing standards established by Congress without incident. *See* 42 C.F.R. § 483.35(a)-(b) (2016).

In 2016, CMS once again dismissed the push for mandatory staffing ratios in LTC facilities and for the 24/7 RN requirement. *See* 81 Fed. Reg. 68,688, 68,754-56 (Oct. 4, 2016). It concluded that a "one-size-fits-all approach" to staffing was not only "inappropriate[,]" but also that "mandatory ratios" and a "24/7 RN presence" were concerning. *Id.* at 68,754-56, 68,758; *see also* 80 Fed. Reg. 42,168, 42,201 (July 16, 2015) (emphasizing the importance of taking resident acuity levels into account"). Specifically, CMS expressed concerns about mandatory ratios and the 24/7 requirement because "LTC facilities [vary] in their structure and in their resident populations." *Id.* CMS determined that the "focus" of its regulations "should be on the skill sets and specific competencies of assigned staff to provide the nursing care that a resident needs rather than a static number of staff or hours of nursing care." 80 Fed. Reg. at 42,201. And "establishing a specific number of staff or hours of nursing care could result in staffing to that number rather than to the needs of the resident population." *Id.* CMS also found that having a 24/7 RN requirement "could negatively impact the development of innovative care options, particular[ly] in smaller, more home-like settings," and that "geographic disparity in supply could make such a mandate particularly challenging in some rural and underserved areas." 81 Fed. Reg. at 68,755.

As CMS acknowledged, there is "widespread variability in existing minimum staffing standards" adopted by 38 States and the District of Columbia. 89 Fed. Reg. at 40,880. CMS found

that obvious when it succinctly explained its rejection of the one-size-fits-all staffing requirement: "The care needs of each of these populations are different. Facilities range in size from the very small to the very large. The capabilities of these facilities are [] different." *Id.* at 68755.

C. CMS issues the Final Rule that departs from past practice

In February 2022, the Biden-Harris Administration departed from decades of practice to establish a "reform" that would "establish a minimum nursing home staffing requirement." White House, FACT SHEET: Protecting Seniors by Improving Safety and Quality of Care in the Nation's Nursing Homes (Feb. 28, 2022) ("White House Fact Sheet").[2] The administration directed CMS to conduct a research study to determine the level and type of staffing needed to accomplish this directive. *Id.*

1. The Abt Study

CMS contracted with a private firm, Abt Associates, to perform a "mixed-methods Nursing Home Staffing Study" as a party of CMS's goal of identifying a minimum staffing requirement.[3] The Biden-Harris Administration's goal was to issue proposed rules establishing minimum staffing requirements by February 2023. So the Abt Study was, "conducted on a compressed timeframe" with data collected between June 2022 through December 2022. Abt Study at xix. The study was completed and published in June 2023.

Consistent with the decades of prior practice, the Abt Study did "not identif[y] a minimum staffing level to ensure safe and quality care." Abt Study at 115. Instead, it found that if a minimum staffing level was imposed, "[n]ursing homes [would] face barriers to hiring, primarily [with] workforce shortages and competition from staffing agencies." *Id.* at xi; *see also*, *e.g.*, *id.* at xii, xiv, 19, 31-32, 115. It concluded that a federal minimum staffing requirement would require between 43 and 90 percent of nursing homes to add more staff; could cost the nursing home industry up to $6.8 billion in compliance costs each year; and would increase annual total salaries per nursing

[2] The White House, *FACT SHEET: Protecting Seniors by Improving Safety and Quality of Care in the Nation's Nursing Homes* (Feb. 28, 2022), available at https://tinyurl.com/3626wt8k.

[3] Abt Associates, *Nursing Home Staffing Study: Comprehensive Report* (June 2023) ("Abt Study") at viii, available https://tinyurl.com/b2ehy528.

home from as low as $316,000 to $693,000 to comply. *Id*. at 113-14.

And there were several relevant findings that the Abt Study did not make:

- The Abt Study did *not* conclude that a minimum staffing requirement would result in *definitive* benefits. The Abt Study provides data for only "*potential* minimum staffing requirement benefits" and for "potential barriers to and unintended consequences of [an] implementation." Abt Study at 121 (emphasis added).
- The Abt Study did *not* conclude that a federally mandated minimum staffing requirement would provide better healthcare outcomes for nursing home residents. Rather, the reviewed literature "underscored" that there was no "clear eviden[tiary] basis for setting a minimum staffing level." *Id.* at xi.
- The Abt Study did *not* find the implementation of a federally mandated minimum staffing requirement to be feasible without considering factors such as variations in resident acuity, ongoing staffing shortages, compliance costs, and the diverse circumstances affecting quality patient care. *Id*. at 32. Rather, there was no "specific evidence" that a minimum nursing staff level could be feasibly implemented. *Id*. at 111.

The absence of these findings is unsurprising given that CMS has previously rejected staffing mandates. *See, e.g.*, 39 Fed. Reg. 2,238, 2,239 (Jan. 17, 1974) (explaining that variation in patients' needs is a valid basis to reject setting a specific staff-to-patient ratio); 45 Fed. Reg. 47,368, 47,371 (July 14, 1980) (rejecting nursing staff ratios or minimum number of nursing hours per patient day because of the lack of conclusive evidence supporting a minimum staffing requirement); 52 Fed. Reg. 38,583, 38,586 (Oct. 16, 1987) (explaining that a 24-hour nursing requirement would be impractical and that a nurse staffing requirement should be sensitive to the "patient mix") ; 80 Fed. Reg. 42,168, 42,201 (July 16, 2015) ("the focus should be on the skill sets and specific competencies of assigned staff to provide the nursing care a resident needs rather than a static number of staff or hours of nursing care that does not consider resident characteristics such as stability, intensity and acuity and staffing abilities including professional characteristics, skill sets and staff mix."); 81 Fed. Reg. 68,688, 68755 (Oct. 4, 2016) ("[w]e do not

agree that we should establish minimum staffing ratios at this time . . . [t]his is a complex issue and we do not agree that a 'one-size-fits-all' approach is best . . . [o]ur approach would require that facilities take into account the number of residents in the facility, those residents' acuity and diagnosis.").

The Abt Study never found that a national, one-size-fits-all approach to minimum staffing requirements would work—despite the Study's own shortcomings. The study failed to reach that conclusion despite its troubling disregard for the ongoing "national health care staff shortages" and "current hiring challenges" that present barriers to nursing homes—which would make compliance with a new federal staffing requirement impractical. Abt Study at xxi. The study acknowledged but ultimately ignored several potential unintended consequences of a national minimum staffing requirement, including: (1) the possibility that nursing homes might be unable to achieve the staffing levels; (2) LTC facilities could be limited in resident admissions because of staff-to-patient ratios; and (3) nursing homes might even close, thereby potentially reducing access to care. *Id.*

2. Promulgation of the Final Rule

CMS issued a proposed rule in September 2023 that introduced new minimum staffing standards for LTC facilities. *See* 88 Fed. Reg. 61352 (Sept. 6, 2023). Despite the 46,000 public comments—some of which warned CMS that the proposed rule exceeded CMS's statutory authority, contravened Congress's considered decision to keep flexible staffing standards, and failed to consider the barriers nursing homes would face with compliance—CMS published the Final Rule in May 2024. *See* 89 Fed. Reg. 40,876.

CMS claims that the minimum staffing standard is supported by "literature evidence, analysis of staffing data and health outcomes, discussions with residents, staff, and industry." *See* 89 Fed. Reg. at 40,877. Citing the inconclusive and truncated six-month Abt Study, CMS claims that this was enough to conclude that an overly-broad staffing requirement was necessary. *See* 89 Fed. Reg. at 40,881, 40,877. Yet, CMS acknowledges that "[t]here is no clear, consistent, and universal methodology for setting specific minimum staffing standards" as evidenced by the 38

states and the District of Columbia that have adopted their own nurse-to-patient ratios. *Id.* at 40881. Notwithstanding the variability across the minimum staffing requirements different states employ, the inconclusive determination of the Abt Study, or the consistent rejection of a one-size-fits-all staffing requirement for over fifty years, CMS published the Final Rule.

CMS asserts that "various provisions" across 42 U.S.C. §§ 1395i-3 and 1396r contain "separate authority" for it to impose the Final Rule. *See* 89 Fed. Reg. at 40,879, 40,890-9:

- The Secretary may impose "such other requirements relating to the health and safety of residents or relating to the physical facilities thereof as the Secretary may find necessary." 42 U.S.C. § 1395i-3(d)(4)(B); *id.* § 1396r(d)(4)(B).
- An LTC facility "must provide services and activities to attain or maintain the highest practicable physical, mental, and psychological well-being of each resident in accordance with a written plan of care." 42 U.S.C. § 1395i-3(b)(2); *id.* § 1396r(b)(2).
- An LTC facility "must care for its residents in such a manner and in such an environment as will promote maintenance or enhancement of the quality of life of each resident." 42 U.S.C. § 1395i-3(b)(1)(A); *id.* § 1396r(b)(1)(A).

3. The Final Rule's Requirements

The Final Rule imposes two mandatory minimum-staffing requirements on LTC facilities. *First*, the Final Rule *triples* the required hours per day of RN services. It requires LTC facilities to have an RN "onsite 24 hours per day, for 7 days a week that is available to provide direct resident care" ("24/7 requirement"). 89 Fed. Reg. at 40997. Meanwhile, the Medicare and Medicaid statutes require that LTC facilities "[u]se the services of [an RN] for at least 8 consecutive hours a day, 7 days a week." 42 U.S.C. § 1395i-3(b)(4)(C)(i); *accord id.* § 1396r(b)(4)(C)(i). *Second*, the Final Rule abandons the flexible, qualitative statutory requirement that LTC facilities "provide 24-hour licensed nursing services which are sufficient to meet the nursing needs of its residents." 42 U.S.C. § 1395i-3(b)(4)(C)(i); *accord id.* § 1396r(b)(4)(C)(i). Instead, the Final Rule requires that "[t]he facility must meet or exceed a minimum of 3.48 [HPRD] for total nurse staffing," which must include a "minimum of 0.55 [HPRD] for registered nurses," and a "minimum of 2.45 [HPRD]

for nurse aides." 89 Fed. Reg. at 40996. Previously, federal regulations mirrored Congress's *qualitative* statutory requirements to keep nursing staff available 24-hours per day. *See* 42 C.F.R. § 483.30. Those regulations never specified a *quantitative* staffing requirement. *Id.*; *Cf.* 89 Fed. Reg. 40,876, 40,996-97.

As to the statutory waivers, the Final Rule permits Medicare participants to qualify for a statutory waiver of the 24/7 RN requirement, but not the HPRD requirements. *Id.* at 40,997-98. The Final Rule also permits Medicaid participants to qualify for the statutory waiver concerning the new 24/7 RN requirement and 0.55 RN HPRD requirement, but not for the 3.48 total nurse HPRD nor 2.45 NA HPRD requirements. *Id.* at 40,997. The Final Rule proposes a "hardship exemption," ostensibly allowing partial relief from the 24/7 requirement and minimum HPRD requirements. *Id.* at 40,998.

Departing from the statutory waiver criteria, the Final Rules requires a facility to establish that it meets all four regulatory requirements to qualify: (1) proving a significant local shortage of health care staff; (2) demonstrating unsuccessful recruitment efforts despite offering competitive wages; (3) documenting financial expenditures on staffing relative to revenue; and (4) qualified facilities must publicly disclose their exemption status. *Id.* at 40,998. Even *if* granted on the case-by-case determination, *see* 89 Fed. Reg. at 40886, the exemption only gives an 8-hour reprieve from the 24/7 RN requirement, leaving facilities with the requirement to staff for at least 16 hours per day, 7 days per week. *Id.* at 40,998. LTC facilities struggling with staffing recruitment or retention will be incapable of qualifying for this "hardship exemption."

4. CMS's Omissions from the Final Rule

CMS fails to adequately explain why it imposed the 24/7 requirement and departed from both the Medicare and Medicaid Acts' statutory 8/7 requirements. Nowhere does the Abt Study suggest that LTC facilities should require an on-site RN 24 hours per day, 7 days per week. CMS fails to explain how it determined its 3.48, 0.55, or 2.45 HPRD requirements. It claims that the 3.48, 0.55, and 2.45 HPRD levels "were developed using case-mix adjusted data sources." 89 Fed. Reg. at 40,877. CMS claims that the 0.55 and 2.45 levels, but not the 3.48 level, were discussed

during the notice of proposed rulemaking. *See* 88 Fed. Reg. 61,352 (Sept. 6, 2023); 89 Fed. Reg. at 40,891.

In the notice of proposed rulemaking, CMS suggested that based on findings from the Abt Study, additional data sources, "two listening sessions," and literature reviews, they proposed minimum staffing levels of 0.55 HPRD for RNs and 2.45 HPRD for NAs. 88 Fed. Reg. at 61369. But the Abt Study does not substantiate those specific levels. And a "review of existing literature" does not give a valid evidentiary basis for establishing these requirements. CMS also fails to establish how other data assessments support the published staffing levels. CMS provides no rationale for the 3.48 HPRD requirement in either the notice of proposed rulemaking or the Final Rule, aside from vaguely stating it was developed using "case-mix adjusted data sources." 89 Fed. Reg. at 40,877.

CMS's minimum staffing ratios require LTC facilities to ignore the variability in resident acuity and needs across different facilities. Some facilities with higher acuity residents may need greater staffing, while others with lower acuity residents may not require an RN present 24/7. CMS fails to explain why requiring facilities with lower acuity residents to maintain higher staffing than needed is necessary for increasing quality of care. CMS fails to consider the ongoing shortage of nursing staff across the country and only offers $75 million to help "increase the [LTC] workforce" that it "expects" will be used for "tuition reimbursement." 89 Fed. Reg. 40,885-86. $75 million is a minuscule fraction of what is *needed* to comply or alleviate many of the affected LTC facilities, and it fails to address the foundational problem. Therefore, LTC facilities will ultimately be on the hook for the remaining $43 billion compliance cost of the Final Rule without assistance from the federal government.

D. The Plaintiffs

Plaintiffs are 20 states, 2 LTCs, and 17 non-profit organizations that represent LTC members in 21 states. All are suffering, and will continue to suffer economic and other harms from the Final Rule. According to the Final Rule itself, the costs are projected to exceed $5 billion per year after the rule is fully implemented. 89 Fed. Red. at 40,970, tbl. 22; *see id.* at 40,949. Outside

studies have placed the cost of even reaching more than $7 billion. *Id.* at 40,950. These costs are immensely burdensome to the LTC facilities' operations as well as to the States.

The Final Rule already is imposing large financial and administrative burdens on LTCs, and those burdens will only increase as the full implementation gets closer. For example, consider Wesley Commons, an LTC facility which is one of plaintiff LeadingAge South Carolina's members. Wesley Commons hired two additional RNs to ensure it can comply with the Final Rule's EFA and 24/7 RN requirements when it goes into effect, incurring extra costs of $14,650, excluding night and weekend shifts, and also reinstated two full-time nursing assistants to ensure it can comply with the HPRD requirement, incurring additional costs of $66,560 per year. *See* South Decl. ¶ 6. It also increased pay to retain and recruit more staff due to the Final Rule's staffing mandates, with the increases costing an additional $164,428 per year. The facility already was in compliance with existing state and federal staffing requirements. *Id.* As another example, South Carolina Baptist Ministries of Aging paid over $1.25 million in 2022 to staffing agencies. In 2024 alone, to come into compliance with the Final Rule, it paid an additional $500,000 to staffing agencies ahead of time to come into compliance. *Id.* ¶ 7(b). Many other LTCs are similarly engaged in advanced hiring, making staff changes, providing enhanced benefits, and increasing recruitment efforts now to ensure they can comply. *See* Van Ree Decl. ¶¶ 8-9; Andrews Decl. ¶ 11.

LTCs that have not already hired staff to comply with the Final Rule soon will do so, and those costs impose significant, and in many cases, impossible, burdens on LTCs. Those burdens are especially harmful in those in rural areas in which the required workforce simply doesn't exist or in other tight labor markets where LTC facilities compete with hospitals and other higher-paying healthcare jobs for scarce healthcare professionals. *See, e.g.*, Monger Decl. ¶ 10 (Kansas needs an additional 312 RNs and 601 NAs to meet the minimum staffing ratios, on top of the existing 2,360 RN and 663 NA job openings); Pezzano Decl. ¶¶ 15-30 (describing workforce shortages and additional yearly cost for Pennsylvania LTC facilities to meet the federal mandate of $462.8 million, or an average of over $689,000 per provider). In these settings, many nursing homes will not be able to absorb the costs of the Final Rule year after year as they continue to rely

on historically underfunded Medicaid and Medicare reimbursement and serving seniors in their communities who cannot afford the escalating cost of the care they need. Nursing homes will incur substantial costs, and they may be required to rely on temporary staffing agencies, which are significantly more expensive, sometimes multiple times the cost of an employed staff member, and notorious for providing lower quality care by those less familiar with and less invested in the residents' wellbeing. These increased costs will likely lead to reduced services and closures for many nursing homes, ultimately reducing long-term care availability for seniors and forcing many to facilities far from their family and friends. *See, e.g.*, Monger Decl. ¶¶ 10, 12 (Kansas); Dowers Decl. ¶¶ 8, 10 (Oklahoma); Pezzano Decl. ¶¶ 15-30 (Pennsylvania); Hinker Decl. ¶¶ 7-8 (South Dakota).

The Final Rule is imposing additional harm on Plaintiffs through its EFA requirement. *See, e.g.*, Monger Decl. ¶¶ 7-9. Implemented on August 8, 2024, the EFA requires providers to conduct a comprehensive evaluation of their facility, residents, staff, and resident families to determine staffing and other needs. The Final Rule mandates LTC facilities to ensure the "active involvement" of direct care staff and their representatives, and to "solicit and consider input" from residents, their representatives, and family members. 89 Fed. Reg. at 40,908; *id.* at 40,905-06. Facilities must "review and update" the EFA at least annually, without clear guidance on when updates are "necessary"—thus, leading to potential civil penalties. *Id.* at 40,999. LTC facilities must also create "contingency planning," despite already having emergency plans in place. *Id.* at 41,000.

The EFA imposes significant administrative burdens and vague requirements that could result in fiscal penalties even with LTC facilities seeking to comply in good faith. CMS estimates the cost of the EFA to be around $4,955 per facility, but that number is too low. An LTC member of LeadingAge Minnesota has spent over $10,000 on administrative costs on the EFA—more than double CMS' estimate—but does not know if its attempt will be found compliant or not. Thurlow Decl. ¶ 7. As another example, Plaintiff Dooley Center took about 16 hours of staff time to complete the enhanced facility assessment, which comes out to approximately $579.36 per month to stay in compliance. Porter Decl. ¶ 9. For plaintiff Wesley Towers, the EFA required 89 hours to

complete, costing thousands of dollars of staff time and diverting their attention from other work. Mains Decl. ¶ 5. Underscoring the arbitrary nature of the Final Rule's staffing mandates, both Dooley Center's and Wesley Towers' EFA demonstrated there is no supported need for 24/7 RN coverage, as their acuity is low, with no major diagnosis or skill needs requiring an RN on site around the clock. *See* Porter Decl. ¶ 9; Mains Decl. ¶ 4.

The State Plaintiffs that operate their own nursing homes subject to the Final Rule will incur all of these same costs and burdens. *See* Beane Decl. ¶ 6. For example, Idaho has at least five state-run nursing homes subject to the Final Rule. Charron Decl. ¶ 5. These nursing homes and, by extension the State, will suffer the same harms that the LTCs described above suffer, with massively increased staffing costs, an inability to hire necessary staff such that they are forced to reduce services or even close, and increased staff time and costs devoted to EFAs that contain vague directives as to the requirements and frequency. *See* Charron Decl. ¶ 17, Idaho estimates the Final Rule's staffing requirements alone will cost the State at least $800,000 annually, at each LTC facility. *See* Charron Decl. ¶¶ 10.

The harms to the state plaintiffs extend beyond LTC facilities. Take Indiana as an example. There, the Indiana Health Coverage Program and Indiana PathWays for Aging provide coverage for long-term care services provided to eligible members with an applicable level-of-care determination. CMS estimates that complying with the 24/7 RN Requirement will cost over $10.9 million annually in Indiana. 89 Fed. Reg. at 40,962, tbl. 18. Statewide, CMS estimates that complying with this rule will cost Indiana LTD facilities $151.2 million. *Id.* at 40984, tbl. 28. Much of this cost will be passed on to health plans, like Indiana Health Coverage Program and Indiana PathWays for Aging offered by the State. And each state will face increased costs through the Medicaid and Medicare programs, since the minimum staffing requirements will increase the cost of care, those costs will be reimbursed through Medicaid and Medicare, and the federal government does not fully cover those costs. *See* Salter Decl. ¶ 15; *see also* Ahern Decl. ¶¶ 21-26.

The Final Rule also harms the States by substantially increasing their administrative costs necessary for compliance. States must devote staff resources to the Final Rule's institutional

payment transparency reporting requirements. 89 Fed. Reg. at 40,995; *See* Ahern Decl. ¶¶ 5-6; Matney Decl. ¶ 6; Ricci Decl. ¶ 5. And they must maintain the reported information on a public website. The Final Rule acknowledges these costs to the States of $183,851 in the first year. *Id*. at 40,991; *see also* Charron Decl. ¶ 15; Matney Decl. ¶¶ 6-7; Ricci Decl. ¶¶ 6-7. Further, the States will pay to process waiver requests from LTC facilities and to investigate and enforce complaints about LTC facilities' compliance. *See* Charron Decl. ¶¶ 6-8, 13-14; Ricci Decl. ¶¶ 11, 15-21; Ahern Decl. ¶¶ 9-20. And complaints and waivers requests are particularly likely to occur in light of the shortage of trained nurses in nearly every state, which will make strict compliance with the Final Rule nearly impossible. *See* Charron Decl. ¶¶ 7-8, 12; Salter Decl. ¶¶ 6-9.

LEGAL STANDARD

Preliminary injunctive relief is available to plaintiffs who demonstrate: (1) the probability or likelihood of success on the merits, (2) the real threat of irreparable harm or injury absent immediate relief, (3) that the balance of equities resulting from the issuance of the injunction against the order's effect on the defendant and third parties weighs in favor of plaintiffs, and (4) that the public interest favors immediate injunctive relief. *See Dataphase Sys.*, 640 F.2d at 113 (en banc). While likelihood of success on the merits is generally the "most significant" factor, *S&M Constructors, Inc. v. Foley Co.*, 959 F.2d 97, 98 (8th Cir. 1992), "[n]o single factor in itself is dispositive," *Calvin Klein Cosmetics Corp. v. Lenox Labs., Inc.*, 815 F.2d 500, 503 (8th Cir. 1987). All four weigh in favor of such relief here.

ARGUMENT

I. PLAINTIFFS ARE LIKELY TO SUCCEED ON THE MERITS.

A. The Major Questions Doctrine

The huge costs and potential effects across the country render this a major questions doctrine case. Thus the validity of the Final Rule should be viewed through that lens. When agency action involves a matter of "vast economic and political significance," the agency must find clear congressional authority approving of such action. *Alab. Ass'n of Realtors v. Dep't of Health and Hum. Servs.*, 594 U.S. 758, 764 (2021) (finding no clear congressional authority for the CDC to issue

a nationwide eviction moratorium). The requirement of clear congressional authorization is based on "both separation of powers principles and a practical understanding of legislative intent." *West Virginia v. EPA*, 597 U.S. 697, 723 (2022). Courts should "'typically greet' assertions of 'extravagant statutory power over the national economy' with 'skepticism.'" *Id.* (quoting *Util. Air Regul. Group v. EPA*, 573 U.S. 302, 324 (2014)).

Here, the Final Rule is of vast economic and political significance, and thus implicates the major questions doctrine. CMS proposes to revamp the entire nursing home industry to the tune of *at least* $43 billion dollars in compliance costs. The actual cost is likely higher; much higher. The Supreme Court has held that $50 billion qualifies as a Rule of vast economic significance. *Ala. Ass'n of Realtors*, 594 U.S. at 764. Beyond the costs, the breadth of authority CMS now asserts is monumental. The Final Rule would fundamentally alter the landscape of the nursing home industry in a manner that impacts 97% of all nursing homes and will put many of them out of business. Furthermore, it would exceed the minimum staffing requirements for nursing homes in "nearly all states." 89 Fed. Reg. 40,877.

When the major questions doctrine is triggered, as it is here, "clear authorization" and not some "vague statutory grant" is required for a court to find it lawful. *West Virginia*, 597 U.S. at 732. CMS fails this test because they rely *exclusively* on a vague statutory grant that has been in place for decades and does not identify clear authorization. "It is unlikely that Congress will make an extraordinary grant of regulatory authority through vague language in a long-extant statute," such as the ones here. *Id.* at 747 (cleaned up). Even worse, the Final Rule *conflicts* with a separate Congressional statute, and seeks to impose staffing mandates like ones that both Congress and the relevant agencies have rejected repeatedly in the decades since the Medicaid and Medicare statutes were passed. This history underscores the absence of any clear authorization for its promulgation. *Id.* at 731 (rejecting agency action that Congress had already "considered and rejected"). Accordingly, the history of Congress' actions in this area, the "breadth of the authority" CMS now asserts, and "the economic and political significance" of that asserted authority confirm that CMS cannot impose these new staffing mandates. *Id.* at 721.

The major questions doctrine is also implicated given its impact on powers reserved to the States. "When an agency claims the power to regulate vast swaths of American life, it not only risks intruding on Congress's power, it also risks intruding on powers reserved to the States." *Id.* at 744. (Gorsuch, J. concurring). CMS has "intruded" on powers traditionally reserved to the States by forcing this staffing rule on them. Because Congress required only 8/7 staffing and allowed flexibility for LTCs based on the needs of their facilities, states have moved to add further requirements based on the needs of their residents and communities. The Final Rule acknowledges that 38 states and the District of Columbia have adopted their own staffing standards that vary between them. *See* 89 Fed. Reg. 40,881. There is no doubt the major questions doctrine applies here. The only question is whether Defendants flunk that test. They do.

B. CMS Does Not Have any Authorization to Issue the Final Rule

Defendants are required to meet a heavy burden of clear authorization to impose this Final Rule. This they cannot do. Indeed, any reasonable reading of the statute would demonstrate that they do not have even a plausible argument that Congress gave them the authority to implement the Final Rule. CMS, like all administrative agencies, is a "creature[] of statute," and accordingly "possess[es] only the authority that Congress has provided." *Nat'l Fed'n of Indep. Bus.*, 595 U.S. at 117. "[A]n agency literally has no power to act . . . unless and until Congress confers power upon it." *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986); *see also* 42 U.S.C. § 1302(a) (Secretary may not "publish rules and regulations" that are "inconsistent with" the law).

Courts are especially skeptical when an agency uses "a wafer-thin reed on which to rest such sweeping power." *Ala. Ass'n of Realtors*, 594 U.S. at 765. Finally, Congress "does not alter fundamental details of a regulatory scheme in vague terms or ancillary provision-it does not, one might say, hide elephants in mouseholes." *Whitman v. American Trucking Ass'n*, 531 U.S. 457, 468 (2001) (internal citation omitted). For the Final Rule, the agency relies exclusively on elephants hidden in mouseholes. That fails because (1) they use a "miscellaneous" and "other" authority to triple the minimum staffing hours Congress has already implemented, (2) they use that same provision to authorize staffing ratios that are nowhere to be found in the statute, and (3) holding

that the agency does have such authority would cast constitutional doubt upon the statute they claim for authority.

1. The 24/7 RN Requirement

Defendants have no authority to triple the requirement for the minimum amount of RN staffing necessary to participate in Medicaid or Medicare. Congress has already decided the issue: LTC facilities "must use the services of a registered professional nurse for at least 8 consecutive hours a day, 7 days a week." 42 U.S.C. § 1396r(b)(4)(C)(i); *accord id.* §1395i-3(b)(4)(C)(i). The Final Rule nevertheless seeks to alter this statutory requirement by mandating that an LTC "must have a registered nurse (RN) onsite 24 hours per day, for 7 days a week." 89 Fed. Reg. at 40997.

CMS, like all administrative agencies, can only promulgate rules "pursuant to authority Congress has delegated to [it]." *Gonzales v. Oregon*, 546 U.S. 243, 258 (2006). They rely *not* on the statutory provision that directly addresses minimum staffing but "various provisions" elsewhere in sections 1395i-3 and 1396r that contain "separate authority" for this novel requirement, *id.* at 40879, 40890-91, pointing to provisions that: (1) an LTC must meet "such other requirements relating to the health and safety of residents or relating to the physical facilities thereof as the Secretary may find necessary," 42 U.S.C. § 1396r(d)(4)(B), *accord* 42 U.S.C. § 1395i-3(d)(4)(B); (2) An LTC facility "must provide services and activities to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident in accordance with a written plan of care," 42 U.S.C. § 1396r(b)(2), *accord* 42 U.S.C. § 1395i-3(b)(2); and (3) An LTC facility "must care for its residents in such a manner and in such an environment as will promote maintenance or enhancement of the quality of life of each resident." 42 U.S.C. § 1396r(b)(1)(A); *accord* 42 U.S.C. § 1395i-3(b)(1)(A).

None of those provide the authority CMS needs to justify issuing the Final Rule. Indeed, the only section that allows authority for CMS to engage in rulemaking at all is 42 U.S.C. § 1396r(d)(4)(B), *accord* 42 U.S.C. § 1395i-3(d)(4)(B), which requires LTCs to "meet such *other* requirements relating to the health, safety, and well-being of residents or relating to the physical facilities thereof as the Secretary may find necessary." (emphasis added). This provision is housed

under a subheading of "Other," which, in turn, is housed under a subheading of "Miscellaneous," which, in turn, is housed under a subheading "Requirements relating to administration and other matters." *Id.* The best reading of the statutory authority that CMS relies on is that it is related to administrative details concerning the health and safety of LTC patients which the rest of the Medicare and Medicaid statute does not already cover.

But Congress addressed the mandatory hours for nurse staffing for LTCs in a separate statutory provision, and it is implausible that CMS could have given CMS authority to alter that standard through rulemaking in a "miscellaneous" statutory provision. None of the other general laws CMS relies on gives it that authority either. That's because "[g]eneral language" in one part of a statute "will not be held to apply to a matter specifically dealt with in another part of the same enactment." *See, e.g.*, *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 645-46 (2012) (quoting *D. Ginsberg & Sons, Inc. v. Popkin*, 285 U.S. 204, 208 (1932)).

CMS recognized that the statutory provisions establishing the 8/7 requirement did not give it authority to that congressionally-enacted standard, as it disclaimed any reliance on those provisions. *See* 89 Fed. Reg. at 40,891. Yet CMS still blundered forward, even expressly recognizing that the Final Rule "revises" the statutory 8/7 RN requirement. *See* 89 Fed. Reg. at 40,996. Congress did not give CMS the authority to "revise" a statute. The 24/7 provision of the Final Rule lacks a colorable textual basis, much less clear authorization.

2. The HPRD Requirements

The Final Rule's HPRD requirements fare no better as they are not mentioned anywhere in the statute. Congress carefully considered whether to enact quantitative staff-to-patient ratios for LTC facilities, and it chose not to do so. Congress chose a qualitative standard in the underlying statutes, leaving quantitative staff-to-patient ratios to the states: LTC facilities must provide nursing services "sufficient to meet the nursing needs of its residents." 42 U.S.C. § 1396r(b)(4)(C)(i); *accord* § 1395i-3(b)(4)(C)(i). The Final Rule unlawfully substitutes CMS's current policy views for Congress' considered judgment. Instead of accommodating the wide variation of resident needs in different states and communities, the Final Rule inflexibly mandates

that each facility in each state meet an arbitrary numerical staffing threshold: "[a] minimum of 3.48 hours per resident day for total nurse staffing[,] including but not limited to—(i) [a] minimum of 0.55 hours per resident day for registered nurses; and (ii) [a] minimum of 2.45 hours per resident day for nurse aides." 89 Fed. Reg. at 40996.

Once again, CMS does not rely on § 1395i-3(b)(4)(C) or § 1396r(b)(4)(C) as authority for these new requirements. And once again, CMS invokes the Secretary's "miscellaneous" authority to make "other" rules that Congress did not already cover for the health and safety of residents, as well as provisions requiring LTC facilities to "provide services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident," and "promote maintenance or enhancement of the quality of life of each resident." 89 Fed. Reg. at 40879, 40890-91; *see* 42 U.S.C. §§ 1395i-3(b)(1)(A), (b)(2), (d)(4)(B); 1396r(b)(1)(A), (b)(2), (d)(4)(B).

None of those generalized provisions authorize CMS to impose nationwide HPRD requirements for RNs, NAs, and total nursing staff. CMS's general authority over Medicare and Medicaid does not permit it to modify "matter[s] specifically dealt with in another part of the same enactment." *RadLAX Gateway Hotel*, 566 U.S. at 646; *see also* 42 U.S.C. § 1302(a) (the Secretary may not promulgate regulations that are "inconsistent with" statutory requirements).

Congress weighed what staffing levels to require from LTC facilities, and it required that each facility maintain staffing levels "sufficient to meet the nursing needs of its residents." 42 U.S.C. §§ 1396r(b)(4)(C), 1395i-3(b)(4)(C). CMS cannot use general authority to supersede Congress' judgment with its own arbitrary numerical requirements. Simply put, CMS has no right to override Congress' judgment.

3. Constitutional Doubt

If Congress intended to give CMS such vast power in a catchall provision, it would cast constitutional doubt on the statute itself. The constitutional doubt canon requires this Court to interpret the Rule to avoid these severe constitutional problems. As the Supreme Court has explained, its "application of the nondelegation doctrine principally has been limited to the interpretation of statutory texts, and, more particularly, to giving narrow constructions to

statutory delegations that might otherwise be thought to be unconstitutional." *Mistretta v. United States*, 488 U.S. 361, 373, n.7 (1989). The Supreme Court thus reads statutes with this principle in mind, *see, e.g.*, *Gundy v. United States*, 139 S.Ct. 2116 (2019), and this Court should do the same.

If Congress truly gave CMS the authority to implement a regulation that costs at least $43 billion to comply with and overrides another one of its provisions, then it supplied no intelligible principle to guide how that power should be exercised. If CMS' interpretation was accepted as the one Congress intended it would present serious nondelegation concerns. *See Kentucky v. Biden*, 23 F.4th 585, 607, n.14 (6th Cir. 2022). ("If the government's interpretation were correct—that the President can do essentially whatever he wants so long as he determines it necessary to make federal contractors more 'economical and efficient'—then that *certainly* would present non-delegation concerns."). The Court need not go that route as it can conclude (correctly) that the agency simply does not have the statutory authority it claims.

C. The Final Rule conflicts with statute

Even if CMS had some authority to set staffing requirements through vague statutory provisions, it could not use that limited authority to contradict what Congress had already put into place. "Agencies may play the sorcerer's apprentice but not the sorcerer himself." *Alexander v. Sandoval*, 532 U.S. 275, 291 (2001). The Final Rule is a crude attempt by CMS to play sorcerer.

Congress has already established the minimum amount of RN staffing necessary to participate in Medicaid or Medicare: LTC facilities "must use the services of a registered professional nurse for at least 8 consecutive hours a day, 7 days a week." 42 U.S.C. §1396r(b)(4)(C)(i); *accord id.* § 1395i-3(b)(4)(C)(i). The Final Rule rewrites this statutory requirement in two ways. *First*, it requires 24-hour nursing care for all nursing homes unless they get a waiver. It does this by replacing the 8/7 RN requirement enacted by Congress with a mandate that all LTC facilities "must have a registered nurse (RN) onsite 24 hours per day, for 7 days a week." 89 Fed. Reg. at 40,997.

As noted above, Congress only requires 24-hour nursing staff sufficient to meet the nursing needs of nursing home patients. 42 U.S.C. §1396r(b)(4)(C)(i)(I). Congress intended for

at least *some* situations where 24-hour nurse staffing at nursing homes would not be required without seeking a waiver. Otherwise the 8/7 staffing rule and language allowing flexibility in 24-hour staffing requirements would be reduced to mere surplusage as every single LTC facility (absent a waiver) would be required to have 24-hour nurse staffing. But Congress did not do that. Therefore, any agency rule that requires mandated hours must at a minimum be less than 24 hours. By requiring 24-hour nurse staffing for *all* nursing homes, CMS has directly contradicted the statute it claims to interpret. This they cannot do.

Second, the Final Rule's waiver provisions only provide an 8-hour per day exemption to the 24-hour staffing. 89 Fed. Reg. 40,953. This means that a nursing home will never be allowed to have less than 16 hours of nursing staff per day. The statute on the other hand provides waivers *even to its* 8/7 staffing requirements. *See* 42 U.S.C. § 1396r(b)(4)(C)(ii); *accord* § 1395i-3(b)(4)(C)(ii). The Final Rule would make this statutory waiver provision null and void as no one could receive the exception Congress explicitly provided by statute. This cuts against the presumption against ineffectiveness in statutory interpretation. This canon holds that a textually permissible interpretation that furthers rather than obstructs the document's purpose should be favored. *See* A. Scalia and B. Garner, *Reading Law: The Interpretation of Legal Texts* 63-65 (2012). The court should not favor CMS' interpretation of the statute as the statute's waiver provision would be ineffective if that were the case.

D. The Final Rule is arbitrary and capricious.

Beyond contradicting the statute, the Final Rule is the very definition of arbitrary and capricious rulemaking. The APA's arbitrary-and-capricious standard requires agency action to be "reasonable and reasonably explained." *E.g.*, *Texas v. United States*, 40 F.4th 205, 226 (5th Cir. 2022) (quoting *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021)). The court "must set aside any action premised on reasoning that fails to account for relevant factors or evinces a clear error of judgment." *Id.*

An agency acts arbitrarily and capriciously when it departs sharply from prior practice without reasonable explanation or fails ignores alternatives to its action or the affected

communities' reliance on the prior rule. *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1913 (2020). The standard is also met when an agency "relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *In re Operation of Mo. River Sys. Litig.*, 421 F.3d 618, 628 (8th Cir. 2005).

Ignoring costs is a failure to consider an important part of the problem. *Michigan v. EPA*, 576 U.S. 743, 752-53 (2015). "Agencies have long treated cost as a centrally relevant factor when deciding whether to regulate. Consideration of cost reflects the understanding that reasonable regulation ordinarily requires paying attention to the advantages *and* the disadvantages of agency decisions." *Id.* And when an agency changes a longstanding policy, it must "show that there are good reasons for the new policy" and "be cognizant that longstanding policies may have 'engendered serious reliance interests that must be taken into account.'" *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221-22 (2016) (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)).

By promulgating the Final Rule, CMS acted arbitrarily and capriciously because it (1) engaged in a sharp departure from past practice without reasonable explanation, (2) failed to consider reliance interests, and (3) failed to consider important aspects of the problem.

1. Sharp Departure from Past Practice

For 50 years, Defendants have consistently declined to deviate from the plain text of the statute by issuing staffing quotas. For example, the Social Security Administration declined to adopt such a nationwide ratio requirement in 1974. Then, in 1980, HHS expressly declined to propose "any nursing staff ratios or minimum number of nursing hours per patient per day." *See also e.g.*, 45 Fed. Reg. at 47,371. A few years later, an HHS-commissioned study concluded that "prescribing simple staffing ratios is clearly inappropriate."[4] In 2002, the Secretary of HHS

[4] *See* Inst. of Med., *Improving the Quality of Care in Nursing Homes* 102-03 (Mar. 1986), https://archive.ph/KFNCi.

informed Congress that, after studying the issue for several years, it was not recommending the imposition of minimum-staffing ratios on LTC facilities.[5] Most recently, in 2016, CMS again rejected requests to adopt minimum-staffing rules, reiterating that it is not reasonable to adopt "a 'one size fits all' approach" toward LTC facilities. 81 Fed. Reg. at 68,755; *see id.* at 68,754-56, 68,758.

What suddenly happened to depart from this consistent past practice? Nothing meaningful. Defendants rely on a single study commissioned solely as a pretext for doing what they wanted to anyway, which was implement this Final Rule. Even that study did not justify the mandates they are now proposing. The cited study did "not identif[y] a minimum staffing level to ensure safe and quality care." Abt Study at 115. Instead, it found that if a minimum staffing level was imposed, "[n]ursing homes [would] face barriers to hiring, primarily [with] workforce shortages and competition from staffing agencies." *Id*. at xi. While an agency may depart from past practice, it must explain demonstrate there is good reason for doing so. *Encino Motorcars, LLC*, 579 U.S. at 221-22. One study that did not even conclude that the hiring mandates were appropriate or feasible does not cut it. This failure to reasonably explain sharply departing from 50 years of consistent practice is arbitrary and capricious.

2. Failure to Consider Reliance Interests

Even if Defendants reasonably explained their sharp departure from past practice, it does not relieve them of their obligations to consider reliance interests. In the decades that the flexible staffing mandate has been in place, states have responded by implementing staffing requirements tailored to their citizens' needs. In turn, LTCs have devoted considerable resources to meeting the state requirements and working with local lawmakers to achieve a workable standard and ensure that they are complying. CMS concedes that its 24/7 RN requirement imposes a one-size-fits-all requirement, 89 Fed. Reg. at 40,908. Such an approach is not only unworkable in a nation made

[5] Letter from Tommy G. Thompson, Sec'y of Health & Human Servs., to J. Dennis Hastert, Speaker of House of Representatives 1 (Mar. 19, 2002) ("Thompson Letter"), reprinted in *Office of Asst. Sec'y for Planning & Evaluation, Dep't of Health & Human Servs., State Experiences with Minimum Nursing Staff Ratios for Nursing Facilities: Findings from Case Studies of Eight States* app. 1 (Nov. 2003), https://archive.ph/wip/KQWPt.

up of such diverse states, but it also upends decades of an intentional balance by Congress to set a minimum standard that states then may supplement.

A few examples exemplify the unique approaches that states have worked hard to adopt—given their individual circumstances and the realities of their workforce and budgetary landscape—to ensure that their senior citizens are appropriately protected:

- Kentucky does not set a numerical staffing requirement for nursing homes. Rather, Kentucky adopts a flexible approach requiring "twenty-four (24) hour nursing services with a sufficient number of nursing personnel on duty at all times to meet the total needs of residents." 902 Ky. Admin. Reg. 20:048, § 3(2)(a). Although Kentucky requires a charge nurse to be always on duty, a licensed practical nurse may serve in that role if a registered nurse is on call. *Id.* at § 2(10)(l).
- Missouri law requires skilled nursing facilities to have an RN on duty in the facility for the day shift, and either an LPN or RN for both evening and night shifts. An RN also must be on call any time only an LPN is on duty. And all residential care facilities must have at least one employee for every forty residents. In addition, Missouri residential care facilities must employ a licensed nurse for eight hours per week per thirty residents to monitor each resident's condition and medication. 19 C.S.R. § 20-85.042; *id.*§ 30-86.042 & .043.
- North Dakota has, for decades, set a minimum staffing requirement obligating facilities to have an RN on duty for eight hours per day. *See* N.D. Admin. Code § 33-07-03.2-14 (effective July 1, 1996). As of the first quarter of 2023, only *one* of North Dakota's 76 nursing facilities would comply with the Rule's new HPRD standards.
- West Virginia requires each nursing home in the State to have an RN on duty in the facility for at least eight straight hours, seven days a week. W. Va. Code R. § 64-13-8.14.4. If there is not an RN on duty, West Virginia law requires an RN to be on call. *Id.* § 64-13-8.14.5. West Virginia also requires nursing homes to provide at least "2.25 hours of nursing personnel time per resident per day." *Id.* § 64-13-8.14.1.

These varying standards sit alongside wide variations in circumstances within the different states. State Medicaid rates for nursing home services vary from $170 per day to over $400 per day. AHCA Cmt.6. Some states have a steady supply of RNs and NAs, while many others are facing a massive shortage. *See, e.g.*, 89 Fed. Reg. at 40,957, 40,976; 81 Fed. Reg. at 6,755 (noting "geographic disparity in supply" of nursing staff). Rather than "highlight[ing] the need for national minimum-staffing standards," the "widespread variability in existing minimum staffing standards" adopted by 38 States and the District of Columbia underscores that "different local circumstances . . . make different staffing levels appropriate (and higher levels impracticable) in different areas of the country." *Compare* 89 Fed. Reg. at 40,880, *with* AHCA Cmt.6. By imposing rigid nationwide requirements that "exceed the existing minimum staffing requirements in nearly all States," 89 Fed. Reg. at 40877, CMS not only ignored Congress but also state governments whose state-law minimum staffing requirements reflect local conditions.

When an agency upends decades of state laws and practices that LTCs have relied on, it must seriously consider those reliance interests. *Encino Motorcars, LLC*, 579 U.S. at 221-22. Defendants did not do that here. They effectively ignored them by stating in general terms that increased staffing can lead to better outcomes in patients. The general proposition that increased staffing in understaffed facilities can lead to better outcomes is not a reasonable consideration of the reliance interests of both states and LTCs who have had flexibility for decades. Such a failure is arbitrary and capricious.

3. Failure to Consider Important Aspects of the Problem

Finally, the Final Rule is arbitrary and capricious because it fails to consider both the virtual impossibility of complying with the mandates and the staggering costs it puts on LTCs.

First, the Final Rule fails to consider the possibility that it is nearly impossible for many LTCs to comply with the Final Rule. The organizational and provider plaintiffs detail the hardship they already face in hiring staff and the impossibility of implementing the Final Rule's minimum staffing requirements because of the inadequate supply of RNs and NAs in their states and local communities. They also explain how the waivers and exemptions in the Final Rule

provide no realistic assistance to their LTC facilities. *See, e.g.*, Pezzano Decl. ¶¶ 15-30; South Decl. ¶¶ 4-8; Monger Decl. ¶¶ 10-16; *see also* AHCA Cmt.1-2 5, 11-13, 18; Leading Age Cmt.1-2, 4. CMS barely acknowledges this issue, noting merely that the new requirements "exceed the existing minimum staffing requirements in nearly all States" and will require increased staffing "in more than 79 percent of nursing facilities nationwide." 89 Fed. Reg. at 40877.

CMS estimates that LTC facilities will need to hire an additional 15,906 additional RNs to meet the 24/7 RN requirement and 0.55 RN HPRD requirement (an increase of about 11.8%), plus an additional 77,611 NAs to meet the 2.45 NA HPRD requirement and 3.48 total nurse HPRD requirement (an increase of about 17.2%). *See id.* at 40958, 40,977-80. Those increases are unattainable at a time when many LTC facilities are already experiencing extreme difficulty finding qualified RNs and NAs to fill vacant positions, and when staffing shortages are expected only to worsen. *See generally* Bates Decl.; Monger Decl.; Pezzano Decl.; South Decl.; *see also, e.g.*, AHCA Cmt.5; LeadingAge Cmt.1. Put simply, "staffing mandates do not create more caregivers, nor do they drive caregivers to work in long term care." AHCA Cmt.1. The Final Rule also irrationally discounts the vital role of LPNs/LVNs, who hold nearly 230,000 jobs in LTC facilities across the country and undisputedly "provide important services to [their] residents." 89 Fed. Reg. at 40881; *see* Monger Decl. ¶¶ 11, 14; Hinker Decl. ¶ 9; Thurlow ¶ 14; AHCA Cmt.6; LeadingAge Cmt.2. As commenters pointed out, the Final Rule creates an incentive for LTC facilities "to terminate LPN/LVNs and replace them with . . . [less qualified] nurse aides" in order to meet the 2.45 NA HPRD requirement.

What was CMS' response to this mountain of evidence that LTCs will not be able to comply with the Final Rule? It was an irrational conclusion that "[a] total nurse staffing standard will guard[] against" it. 89 Fed. Reg. at 40,893; *see* 88 Fed. Reg. at 61,366, 61,369. But that's obviously wrong. For example, a facility that already provides high-quality care through average staffing of 0.55 RN HPRD, 1.25 LVN/LPN HPRD, and 1.7 NA HPRD would satisfy the 3.48 total nurse HPRD requirement but would need an another 0.75 NA HPRD to satisfy the 2.45 NA HPRD requirement. *See, e.g.*, Porter Decl. ¶ 6 (Dooley Center staffing includes 4.64 total nurse HPRD but

it would have failed the Final Rule's required 0.55 RN HPRD 39% of the time). The Final Rule pressures LTC facilities to replace experienced LPNs/LVNs with less-qualified new hires to meet CMS's arbitrary quota of 2.45 NA HPRD.

The Final Rule does not deny that there are not nearly enough RNs and NAs available to enable the 79 percent of LTC facilities that are not presently in compliance with the agency's new mandates. CMS asserts that the Final Rule's phase-in period will "allow all facilities the time needed to prepare and comply with the new requirements specifically to recruit, retain, and hire nurse staff as needed." 89 Fed. Reg. 40,894. But more time does not mean more nurses will suddenly become available. The Final Rule is a mandate that many LTC facilities will have no realistic way to meet. There is no reason to think that the shortage of RNs and NAs will ease over the next two to three years. In fact, it is projected to become even worse, as "hundreds of thousands are expected to retire or leave the health care profession entirely in the coming years." AHCA Cmt.5; *see id.* at 2 ("The phase-in provisions are frankly meaningless considering the growing caregiver shortage."); LeadingAge Cmt.7 (similar); *see also* Pezzano Decl. ¶¶ 18-21 (describing dire trends in healthcare workforce); Monger Decl. ¶ 10 (similar); Bates ¶ 7 (similar). CMS asserts that it "fully expect[s] that LTC facilities will be able to meet [the Final Rule's] requirements," 89 Fed. Reg. at 40894, but the evidence provided by plaintiffs shows this is anything but true.

CMS' "hardship exemption" does not do anything to alleviate this. For starters, such exemptions are available only to facilities that have been surveyed and cited for failure to meet the new staffing standards—and "facilities cannot request" (or receive) "a survey specifically for the purpose of granting an exemption." 89 Fed. Reg. at 40,902. So instead of being able to proactively explain why it should be entitled to an exemption, facilities that cannot meet CMS's arbitrary requirements will face a perpetual risk of being sanctioned for non-compliance. *See* AHCA Cmt.6, 33-34; LeadingAge Cmt.6 (criticizing CMS's approach as "unnecessarily punitive"). CMS repeatedly emphasizes that the hardship exemption is meant for "limited circumstances," 89 Fed. Reg. at 40,894, and that many facilities in areas of the country with severe shortages of available

RNs and NAs would not qualify for an exemption because there are so many "other requirements" that must be met "to obtain an exemption." *Id.* at 40953. *See also, e.g.*, South Decl. ¶ 7 (describing unachievable nature of waiver and exemptions for LTC facilities); Wallace Decl. ¶ 9 (similar) Monger Decl. ¶ 16 (similar). The complete lack of viable exemptions confirms that Defendants did not consider the virtual impossibility of LTCs increasing staff quotas at a time of nurse shortage.

Second, the Final Rule fails to reasonably consider the staggering costs. According to CMS, the Final Rule will cost over $5 billion per year to implement once fully phased in, *see* 89 Fed. Reg. at 40,949, 40,970. Other estimates place the costs as high as $7 billion per year, *see id.* at 40,950. The Final Rule does not provide any additional funding for Medicare or Medicaid, so CMS "assume[s] that LTC facilities . . . will bear the[se] costs." *Id.* at 40,949. LTC facilities are in no position to take on this huge financial burden. AHCA Cmt.5; LeadingAge Cmt.1-2; THCA Cmt.3. Almost 60 percent of LTC facilities already have negative operating margins; more than 500 LTC facilities closed over the course of the COVID-19 pandemic; and the costs associated with these new staffing mandates would likely force many more facilities to close. AHCA Cmt.5; *see* LeadingAge Cmt.1-2; *see also, e.g.*, Munger Decl. ¶ 12 (estimated costs for Kansas LTCs to comply with Final Rule on minimum staffing standards range between $64 million and $92.7 million in the first year, at an average annual cost of $211,905 per facility); Hinker Decl. ¶ 8 (estimating total cost of $20 million for South Dakota facilities to comply with Final Rule).

CMS's imposition of this massive, unfunded staffing mandate, despite the ongoing workforce crisis and economic realities, is neither "reasonable" nor "reasonably explained." *Cf. Texas*, 40 F.4th at 226. It instead simply touts a new initiative that seeks to encourage people to pursue careers in nursing by "investing over $75 million in financial incentives such as tuition reimbursement." 89 Fed. Reg. 40894. But this "one-time workforce effort" is "a drop in the bucket compared to the funding that will be needed to train [the] additional nursing staff" necessary to meet the new mandates. AHCA Cmt. 23; LeadingAge Cmt.1-2. It "is not going to fix the workforce crisis," and it does practically nothing to offset the $5 billion to $7 billion per year in costs that the Final Rule imposes on LTC facilities. AHCA Cmt.23; LeadingAge Cmt.1-2. This complete

failure to consider the impact of *at least* $43 billion in regulatory costs on LTCs with almost no assistance from the federal government is arbitrary and capricious.

II. PLAINTIFFS SUFFER IRREPARABLE HARM AND THE COURT SHOULD WEIGH THE BALANCE OF EQUITIES IN PLAINTIFFS' FAVOR.

A. The Final Rule Irreparably Harms Plaintiffs.

Absent preliminary injunctive relief, Plaintiffs will suffer irreparable harm from the illegal Final Rule. Plaintiffs cannot recover a remedy of money damages for the harms caused by the Final Rule based on the sovereign immunity of the United States, so the Final Rule's imposition of costs constitutes irreparable harm that only a preliminary injunction can prevent.

The LTC Plaintiffs and the Organizational Plaintiffs that represent LTCs are suffering and will continue to suffer sharply increased financial and administrative burdens that will be too great for many LTCs to bear, leading to reduced services and LTC closures.

Devastating Financial Strain. The Final Rule is estimated to cost each LTC hundreds of thousands of dollars annually to implement. For example, in South Carolina, the estimated implementation cost is over $550,000 *per nursing home*. *See* South Decl. ¶ 4. The cost is even greater in Pennsylvania, where the estimated cost is over $689,000 in additional annual costs per provider. Pezzano Decl. ¶ 15. Most LTCs cannot afford the significant financial strain imposed by the Final Rule and will be forced to serve fewer patients, especially Medicare and Medicaid patients, or close their doors entirely. *See, e.g.*, Van Ree Decl. ¶ 8; Porter Decl. ¶ 12; Mains Decl. ¶ 8; Pezzano Decl. ¶ 24.

Workforce Shortages. Even if the LTCs could afford the devasting additional costs of the Final Rule, hiring the required staff is almost impossible. In Pennsylvania, for example, LTCs would need to hire nearly 800 additional full-time RNs and over 5500 additional full-time nurse aids. *Id.* ¶ 16. But, even if cost were no object, making these additional hires is often not possible due to workforce shortages in the healthcare setting, which are compounded in the long-term care setting. For example, from 2019 to 2023, Pennsylvania lost 15% of its nurse aids—even as the Final Rule would require 5500 *additional* nurse aids. Pezzano Decl. ¶ 17. In Iowa, the number of RNs

declined by 5.5% in 2023 compared to 2022, and it replaced only one-third of those with newly certified RNs. Van Ree Decl. ¶ 6. LTCs are engaging in aggressive efforts to recruit RNs and other staff just to meet their current staffing needs, but still have difficulty because the necessary staff are simply not available. *See* South Decl. ¶¶ 4-5 (describing hiring difficulties and need for additional 411 RNs and 1170 nurse assistants, on top of current 8148 RN job openings and 4984 LPN job openings in South Carolina). When LTCs turn to temporary staffing agencies, their costs skyrocket, if staff is available, and many of these temporary employees lack familiarity with the patients and the higher qualifications that full-time employees possess. *See, e.g.* Reed Decl. ¶ 5(d); Pezzano Decl. ¶¶ 8-10, 38; Monger Decl. ¶ 6.

Current Compliance Burdens. Many LTCs have no other choice but to comply with the staffing mandates already or else they will be left in the dust if they wait until 2026 when the Final Rule is fully in effect (and risk getting sanctioned by Defendants for violating the Final Rule). Because of their ongoing struggles to fill open positions, they must incur higher staffing and recruiting costs now, including costs for signing and retention bonuses, to comply. This harm has already occurred and will continue to occur in the future absent court intervention. *See, e.g.*, Andrews Decl. ¶ 11; Van Ree Decl. ¶ 9; Ciborowski Decl. ¶ 6; South Decl. ¶ 4. Once these hiring decisions are made, the costs associated with them cannot be undone.

Enhanced Facility Assessment. The LTC and Organizational Plaintiffs are also incurring significant costs and administrative burdens, along with the possibility of finds for noncompliance with vague standards, from the Final Rule's requirement of enhanced facility assessments, which are currently in effect and will continue to result in costs for LTCs.

Plaintiff States provide significant evidence of the harm they will suffer due to the Final Rule. First, States which directly operate LTC facilities will suffer similar harms suffered by the non-State plaintiffs. For example, the State of Idaho operates five LTC facilities that participate in Medicare and Medicaid and are subject to the Final Rule. Charron Decl. ¶ 5. Additional costs from the Final Rule's increased staffing requirements alone are estimated at $800,000 per facility, annually. *Id.* ¶¶ 9, 20.

Further, under the Final Rule, Idaho's LTC facilities are required to conduct an EFA within 90 days of publication of the Final Rule. 89 Fed. Reg. at 40,913. Defendants admit the EFA requirement will cost each affected LTC facility $4,955, the true cost is likely closer to $10,000-$25,000. Charron Decl. ¶ 17. Compared to existing facility assessment obligations, the EFAs mandated by the Final Rule are expected, approximately, to cost an additional $5,980-$6,758 per facility. *Id*.

Second, State Plaintiffs will be required to engage in "institutional payment transparency reporting." 89 Fed. Reg. at 40,995. States therefore have had and will continue to devote staff resources to acquiring and organizing the information for those reports. *See* Ahern Decl. ¶¶ 5-6; Matney Decl. ¶ 6; Ricci Decl. ¶ 5. And they will incur additional costs posting these reports to a state website. The Final Rule acknowledges these costs to the States of $183,851 in the first year. *Id*. at 40,991; *see also* Charron Decl. ¶ 15; Matney Decl. ¶¶ 6-7; Ricci Decl. ¶¶ 6-7; Azar Decl. ¶¶ 7-8; Rains Decl. ¶¶ 6-9; Beane Decl. ¶¶ 8-11.

Third, the States will incur additional Medicaid and Medicare expenses due to the increased staffing costs at LTC facilities. Since CMS funds only approximately 84% of Medicaid and Medicare obligations, leaving the States to cover the remaining 16%, States will be forced to spend more money on these programs when the costs of providing care increase under the Final Rule's new staffing requirements. *See* Salter Decl. ¶¶ 15-16; *see also* Ahern Decl. ¶¶ 21-27; Azar Decl. ¶¶ 5-6.

Finally, many Plaintiff states already experience a shortage of trained nurses, and compliance with the Final Rule will be challenging. *See* Charron Decl. ¶¶ 7-8, 12; Salter Decl. ¶¶ 6-9; Rains Decl. ¶¶ 21-22; Raines Decl. ¶ 21. Because not all LTC facilities in the States will be able to comply, the States will incur additional costs due the administrative burdens associated with processing complaints and waiver requests. *See* Charron Decl. ¶¶ 6-8, 13-14; Ricci Decl. ¶¶ 11, 15-21; Ahern Decl. ¶¶ 9-20.

Plaintiffs without a doubt experience unrecoverable financial expenditures and devotion of resources to comply with the active EFA provision and to initiate compliance of the staffing

provisions because of the long and difficult timeline for hiring the necessary staff. *See generally* Plaintiff Declarations. These irreparable harms merit preliminary injunctive relief.

B. The Balance of the Equities and Public Interest Favor Plaintiffs.

The balance of equities "so favors the movant that justice requires the court to intervene to preserve the status quo until the merits are determined." *Nebraska v. Biden*, 52 F.4th 1044, 1046 (8th Cir. 2022) (quoting *Glenwood Bridge, Inc. v. City of Minneapolis*, 940 F.2d 367, 370 (8th Cir. 1991)). Moreover, the merits here involve "substantial questions of law which remain to be resolved" and "the equities favor an injunction considering the irreversible impact" that the Final Rule will have "as compared to the lack of harm an injunction would presently impose." *Id.* (quoting *Walker v. Lockhart*, 678 F.2d 68, 71 (8th Cir. 1982)).

There is no harm to Defendants pausing their attempted usurpation of Congress's role by maintaining the decades-long status quo. In fact, only some of the Final Rule is presently in effect: the enhanced facility assessments of appropriate staffing. The minimum staffing requirements do not become mandatory until 2026, so Defendants suffer *no harm* from pausing those illegal mandates pending judicial review. *See Washington v. Reno*, 35 F.3d 1093, 1103 (6th Cir. 1994) (agency suffers no harm when it is prohibited from acting "in violation of applicable statutory restraints"); On the other hand, LTCs and the States will benefit by not having to incur expenses necessary to prepare for the implementation. Without the requested relief, Plaintiffs will suffer irreparable harm from the illegal Final Rule. *See supra*.

Finally, "[t]here is generally no public interest in the perpetuation of unlawful agency action." *Shawnee Tribe v. Mnuchin*, 984 F.3d 94, 102 (D.C. Cir. 2021). To the contrary, where, as here, Plaintiffs have shown a strong likelihood of success on the merits, it is "a strong indicat[ion] that a preliminary injunction would serve the public interest." *Id.*

III. AN INJUNCTION SHOULD APPLY NATIONWIDE.

This Court should enjoin implementation of the Final Rule nationwide—not just in Plaintiff States and with respect to the organizational plaintiffs' members and the two provider plaintiffs—pending a decision on the merits. "'When a reviewing court determines that agency

regulations are unlawful, the ordinary result is that the rules are vacated—not that their application to the individual petitioners is proscribed.'" *Nat'l Min. Ass'n v. U.S. Army Corps of Engineers*, 145 F.3d 1399, 1409 (D.C. Cir. 1998) (quoting *Harmon v. Thornburgh*, 878 F.2d 484, 495 n. 21 (D.C.Cir.1989)); *see also Barr v. Am. Ass'n of Pol. Consultants, Inc.*, 140 S. Ct. 2335, 2351 (2020) (explaining that when "a provision is declared invalid," it "cannot be lawfully enforced against others."). In such a case, a nationwide injunction is appropriate. *D.C. v. U.S. Dep't of Agric.*, 444 F. Supp. 3d 1, 46-48 (D.D.C. 2020); *see also New York v. United States Dep't of Homeland Sec.*, 408 F. Supp. 3d 334, 351-53 (S.D.N.Y. 2019), aff'd as modified, 969 F.3d 42 (2d Cir. 2020); *Guilford Coll. v. McAleenan*, 389 F. Supp. 3d 377, 397 (M.D.N.C. 2019) (collecting cases); *Jordan v. Pugh*, No. CIV.A. 02-CV-01239MS, 2007 WL 2908931, at *4 (D. Colo. Oct. 4, 2007). Indeed, the APA itself allows a reviewing court to "hold unlawful and set aside agency action," 5 U.S.C. § 706(2), a power that is consistent with a nationwide injunction.

There are also practical and equitable reasons for extending the injunction nationwide. The organizational plaintiffs represent LTC facilities in 21 states, and, with 20 more State plaintiffs, well over half the country is represented. "Crafting a preliminary injunction is an exercise of discretion and judgment, often dependent as much on the equities of a given case as the substance of the legal issues it presents." *Missouri v. Biden*, 112 F.4th 531, 538 (8th Cir. 2024). And the equities favor a nationwide injunction which preserves the national status quo and protects Plaintiffs from the Final Rule's destabilizing effects on nursing homes across the country. *See Rodgers v. Bryant*, 942 F.3d 451, 458 (8th Cir. 2019) (basing scope of injunctive relief on "the extent of the violation established, not by the geographical extent of the plaintiff class") (internal quotations omitted). For Defendants, on the other hand, a nationwide injunction is no different from a limited injunction, and is "no more burdensome to the defendants than necessary to provide complete relief to the plaintiffs." *Id.*

And while an injunction limited to Plaintiff organizations and states would cover most of the country in any case, it would be uneven and unmanageable. "[T]ailoring an injunction to address the alleged harms to the remaining States would entail delving into complex issues and

contested facts that would make any limits uncertain in their application and effectiveness." *Nebraska*, 52 F.4th at 1048. Less than a nationwide injunction would require the organizational plaintiffs to monitor and report their membership rolls to determine which LTCs were members to whom the injunctive relief applies. Meanwhile, other LTCs who are not members, or who do not reside in Plaintiff states, would be forced to compete in an uneven market. This Court should not permit such an inequitable outcome. When an injunction limited to Plaintiffs "would be impractical and would fail to provide complete relief to the plaintiffs," a nationwide injunction is appropriate. *Id.* at 1048.

CONCLUSION

Because Plaintiffs have established that they will succeed on the merits and that the other three factors favor preliminary relief, this Court should preliminarily enjoin Defendants from enforcing the Final Rule. Plaintiffs request oral argument on this motion.

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**Pro Hac Vice forthcoming*
***Pro Hac Vice*